

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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**Date:** 10/3/2012

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## India

**Post:** New Delhi

### **FSSAI clarification on the licenses issued without product approval**

**Report Categories:**

Exporter Guide

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Product Brief

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**Report Highlights:**

On September 10, 2012, The Food Safety and Standards Authority of India (FSSAI) issued an additional clarification on the statutory advisory regarding the issuance of licenses for proprietary foods without product approval. According to the advisory, a product that has received a State or Central Department license, but not been approved by the FSSAI should receive a 'No Objection Certificate (NOC)' or be referred to FSSAI's scientific panel so that the product can comply with Section 22 of the Food Safety and Standards Act (FSSA), 2006.

## General Information:

### Introduction:

On September 10, 2012, the Food Safety and Standards Authority of India (FSSAI) issued an additional clarification on the statutory advisory of August 8 (See GAIN [IN2108](#)) regarding the issuance of licenses for proprietary foods without product approval. According to the advisory, a product that has received a State or Central Department license, but not been approved by the FSSAI should receive a 'No Objection Certificate (NOC)' or be referred to FSSAI's scientific panel so that the product can comply with Section 22 of the Food Safety and Standards Act (FSSA), 2006.

In order to facilitate the process, the FSSAI has directed food safety commissioners of all states to provide a list of such cases. FSSAI will issue 'No Objection Certificate (NOC)', and ensure that the product is approved provided it has a proven safety record. Products without a proven safety record will be referred to the FSSAI scientific panels/scientific committees for a risk assessment and subsequent approval.

**Note:** FSSAI has mandated that all manufacturers/importers/processors must obtain FSSAI approval for introducing any new product which is not on the approved list of products under Food Safety and Standards Regulations (FSSR), 2011.

According to section 22 of FSSA, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods, or any such other articles of food without prior Central Government authorization.

This FSSAI notification is available in their website at: [FSSAI Notification](#). The full text of the notification is also attached below.

For further details on the product approval procedure and licensing, please refer to the following GAIN reports.

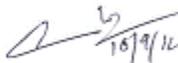
<a href="#">IN2053</a>	FSSAI introduces product approval procedure in India
<a href="#">IN2054</a>	Approval Procedure of proprietary products manufactured or imported products
<a href="#">IN2068</a>	FSSAI Additional Advisory on Product Approval Procedure
<a href="#">IN2104</a>	FSSAI Extends Time Period on Renewal of Licenses and Registration
<a href="#">IN2108</a>	FSSAI releases fresh advisory on product approval procedures

No.1(56)/2012/Advisory/FSSAI  
Food Safety and Standards Authority of India  
Ministry of Health & Family Welfare, Govt. of India  
FDA Bhawan, Kotla Road  
New Delhi-110002.

Dated the 10<sup>th</sup> September, 2012.

Subject:- Details of the licenses issued without Product Approval (case where PA was requested) – Reg.

This is in continuation with the Statutory Advisory issued on 4.7.2012 regarding issuance of licenses for proprietary foods without product approval. The FSS Act, 2006 stipulates that all manufacturers/processors/importers who will be introducing any such new product which is not as per the approved list of products under FSS Regulations, need to obtain product approval. In this regard, the State Food Safety Commissioner is requested to provide details of all such cases where licenses were issued for such products. Cases where licenses were issued for such products which were not approved and product approval was required from Central Authority as per Section 22, may be sent to FSSAI so that further action can be taken. All such products will have to be granted provisional NOC or referred to the Panel as per procedure for further action. After obtaining product approval, licenses may be issued by State or Central Dos as per the production capacity/Turnover ( as the case may be). However, till the time product has not been approved by FSSAI and FBO is working on the NOC, the FBO needs to take Central License. This is necessary as product is only provisionally allowed and is not an approved product and will thus be covered under section 22.

  
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To

All Commissioners of Food Safety of States/UTs.

Copy to :

1. PPS to CP
2. PS to CEO
3. All Directors, FSSAI
4. All Central DOs/AOs
5. Website, FSSAI